K111540

SYNTHES®

AUG - 8 2011

3.0 510(k) Summary

Date Prepared: May 31, 2011

Sponsor:

Synthes (USA)
Thomas N. Shea
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941

Device Name: Synthes 3.5mm LCP Clavicle Plate System

Classification: Class II, §888.3030 – Single / multiple component metallic bone fixation appliance and accessories.

Predicate Devices:

Synthes 2.7/3.5mm VA-LCP Anterior Clavicle Plate System **(K101536)**

Synthes 3.5mm LCP Clavicle Plate System **(K073186)**

Synthes Small Fragment Dynamic Compression Locking System **(K000684)**

Device Description: The Synthes 3.5mm LCP Clavicle Plate System consists of metallic plates and screws that offer screw to plate locking designed for various fracture modes of the clavicle.

Intended Use: The Synthes 3.5mm LCP Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

Substantial Equivalence: The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of the subject components to the predicate devise in terms of mechanical strength. In addition, the intended use, manufacturing methods, packaging, and sterilization of the predicate and subject components are identical.

The subject and predicate devices are made from stainless steel and titanium alloy. Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject Synthes 3.5mm LCP Clavicle Plate System to the predicate devices.

Testing conducted to support the substantial equivalence for the Synthes 3.5mm LCP Clavicle Plate System was performed to assess the bending strength of the subject device compared to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
% Mr. Thomas N. Shea
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

AUG - 8 2011

Re: K111540
Trade/Device Name: Synthes 3.5mm LCP Clavicle Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: May 31, 2011
Received: June 2, 2011

Dear Mr. Shea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

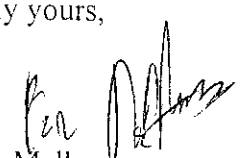
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use

510(k) Number (if known): K111540

Device Name: Synthes 3.5mm LCP Clavicle Plate System

Indications for Use:

The Synthes 3.5mm LCP Clavicle Plate System is indicated for fixation of fractures, malunions, non-unions, and osteotomies of the clavicle in adults, and in both adolescents (12-18 years) and transitional adolescents (18-21 years), in which the clavicular growth plates have fused or in which the growth plates will not be crossed by the plate system.

Prescription Use X (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Mellerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111540